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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,436	09/06/2005	Silvio Aime	57708/380	7608
35743 7590 09/15/2009 KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER SCHLENTZ, LEAH H				
ART UNIT 1618		PAPER NUMBER		
NOTIFICATION DATE 09/15/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

### Office Action Summary

**Application No.**

10/522,436

**Applicant(s)**

AIME ET AL.

**Examiner**

LEAH SCHLIENTZ

**Art Unit**

1618

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,6,7 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,12,13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgement of Receipt***

Applicant's Response, filed 5/18/2009, in reply to the Office Action mailed 11/18/2008, is acknowledged and has been entered. Claims 1, 2, 14 and 15 have been amended. Claims 2, 4, 5 and 8-11 have been cancelled. Claims 1, 3, 6, 7 and 12-15 are pending, of which claims 14 and 15 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 1, 3, 6, 7, 12 and 13 are readable upon the elected invention and are examined herein on the merits for patentability.

### ***Response to Arguments***

Any rejection not reiterated herein has been withdrawn as being overcome by amendment. Applicant's arguments have been fully considered but they are not persuasive for reasons set forth hereinbelow.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kabalka *et al.* (*Mag. Res. in Medicine*, 1988, 8, 53, p. 89 – 95), as evidenced by Encyclopedia Britannica Article, "Reticuloendothelial System," in view of Ranney (US 5,155,215), for reasons set forth in the previous Office Action.

Applicant argues on pages 11-12 of the Response that Kabalka fails to teach or suggest a method of cellular labeling where administered insoluble particles are degraded by enzymes specific to the cell type whose detection is sought. Applicant argues that instead Kabalka merely describes concentration of liposomes in macrophage rich organs, and that degradation is due to "the more labile nature of the ester linkage in the acidic environment of the liver."

This is not found to be persuasive. The claims are not limited to any specific enzymes, and include degradation by "effectors in the environment surrounding the particles." Furthermore, degradation of ester can be achieved by esterases.

Applicant further argues that Kabalka only enables imaging of an organ, not a cell type processing specific degradatory enzymes, and that in Kabalka local macrophages in the organ engulf the liposomes, thus allowing imaging of the organ. Applicant argues that Kabalka fails to teach degradation into single units of paramagnetic chelate useful for MRI, and that Kabalka teaches away from degradation as means of imaging and that Kabalka touts the long half-life of the liposomes in liver.

This is not found to be persuasive. Given the broadest reasonable interpretation of the intended use of the claims for "cellular labelling," MRI would provide images of cells within the organ which have taken up the contrast agent (e.g. RES cells in liver, for example). Regarding Applicant's argument that Kabalka does not teach degradation to single unit paramagnetic chelate, Kabalka teaches degradation to Gd-DTPA on page 94. With respect to Applicant's argument that Kabalka teaches away from degradation

as a means of imaging, touting the long half-life of liposomes in liver, Applicant's claims include increasing lifetime of particles in blood, see dependent claim 12.

***New Grounds for Rejection***

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6, 7, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kabalka *et al.* (*Mag. Res. in Medicine*, 1988, 8, 53, p. 89 – 95), as evidenced by Encyclopedia Britannica Article, "Reticuloendothelial System," in view of Ranney (US 5,155,215), for reasons set forth in the previous Office Action.

With regard to claim 7, Ranney teaches Mn as a functionally equivalent paramagnetic metal ion to Gd (see claim 9).

With regard to claim 12, liposome components of Kabalka increase the lifetime of particles in blood.

With regard to claim 13, Ranney teaches the benefits of targeted imaging such as for uptake by receptors, see column 9, lines 60+.

***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is (571)272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

LHS